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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 08/556,038 11/09/95 BOUSSIOTIS V RPI-022CP **EXAMINER** HM22/0919 LAHIVE & COCKFIELD, LLP GAMBEL, P 28 STATE STREET ART UNIT PAPER NUMBER BOSTON MA 02109 22 1644 **DATE MAILED:** 09/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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DETAILED ACTION

- 1. The request filed 7/17/00 (Paper No. 21) for a Continued Prosecution Application (CPA) under 37 CAR 1.53(d) based on parent Application No. 08/556,038 is acceptable and a CPA has been established An Office Action on the CPA follows.
- 2. Applicant's amendment, filed 4/12/99 (Paper No. 16), is acknowledged. Claims 1-4, 49-71, 76, 92, 99-101 have been canceled previously.

Claims 48, 72-75, 77-91, 93-98 and 102 are pending.

Given applicant's previous request, filed 4/12/99 (Paper No. 16), to extend the search to remaining species of previously elected Group II; the following Restriction is set forth for applicant to determine which Invention/species to prosecute in the instant application.

- 3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 48, 72-75, 77-91, 93-97 and 102, drawn to methods of inhibiting T cell responsiveness with anti-cytokine antibody antibodies; classified in Class 424, subclass 145.1.
- II. Claims 98, drawn to methods of inhibiting anergic T cell responsiveness with an agent which transduces a signal via the cytokine receptor chain; classified in Class 424, subclass 130.1.
- 4. Inventions I and II are different methods; which require different ingredients, process steps and endpoints. Therefore, they are patentably distinct.

As pointed out previously, it was noted that amended claim 98 recites "inhibiting response in an anergic T cell". Given that anergic T cells are considered unresponsive, inhibiting said anergic T cells would be considered as stimulating responses in said T cells.

- 5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and Groups I and II have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter; restriction for examination purposes as indicated is proper.
- 6. This application contains claims directed to the following patentably distinct species of the claimed Group I: wherein the agent is:
 - A) anti-IL-4 antibody,
 - B) anti-IL-7 antibody,
 - C) anti-IL-15 antibody, or
 - D) anti-y chain antibody.

These species are distinct because their physicochemical properties are different, which, address different targets

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 48 (see note) and 102 are generic.

Applicant should note that dependent claim 90 recites anti-γ chain antibody, while the ultimate independent claim 48 does not recite the anti-γ chain antibody as an agent in the claimed methods.

Applicant should carefully review the recitation and dependency of the claimed methods.

7. In addition to electing a species from Section 6; applicant is required a species from the following.

This application contains claims directed to the following patentably distinct species of the claimed Group I: wherein the antigen is:

- A) an alloantigen or
- B) an autoantigen.

These species are distinct because their physicochemical properties are different, which address different pathological conditions and therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 48 (see note above), 83 and 102 are generic.

8. In addition to electing a species from Sections 6/7; applicant is required a species from the following.

This application contains claims directed to the following patentably distinct species of the claimed Group I: wherein the methods is performed:

- A) in vitro,
- B) in vitro further comprising administering the T cell to a subject or
- B) in vivo.

These species are distinct because they require different reagents and method steps.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 48 (see note above), 83 and 102 are generic.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

- 10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 18, 2000